Cryosurgical Ablation of Primary or Metastatic Liver Tumors

**Description**

Cryosurgical ablation involves the freezing of target tissues, most often by inserting into the tumor a probe through which coolant is circulated. Cryosurgical ablation can be performed as an open surgical technique or percutaneously or laparoscopically, typically with ultrasound guidance.

**FDA REGULATORY STATUS**

Several cryosurgical devices have been cleared by the U.S. Food and Drug Administration (FDA). For example, the Endocare™ Cryocare System (Endocare, Irvine, CA) was cleared for marketing through the 510(k) process in December 1996 for "use in general surgery, dermatology, neurology, thoracic surgery, ENT [ears, nose, throat], gynecology, oncology, proctology and urology for the ablation of tissue, including liver metastases, skin lesions, warts, and removal of prostate tissue." Product code: GEH.

**POLICY STATEMENT**

Cryosurgical ablation of either primary or metastatic tumors in the liver is **investigational**.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

**RATIONALE**

**Summary of Evidence**

The evidence for the use of cryosurgical ablation in individuals with unresectable primary hepatocellular carcinoma amenable to locoregional therapy includes 1 randomized controlled trial (RCT), several nonrandomized comparative studies, and multiple noncomparative studies. Relevant outcomes are overall survival, disease-specific survival, and treatment-related morbidity and mortality. The single available RCT comparing cryoablation and radiofrequency ablation (RFA) demonstrated lower rates of local tumor progression with cryoablation, but no differences in survival outcomes between groups.
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Although this study provides suggestive evidence that cryoablation is comparable to RFA, the study has several limitations that suggest findings need to be replicated. Additional comparative evidence is needed to allow conclusions about the effectiveness of cryoablation compared with other locoregional therapies. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for the use of cryosurgical ablation in individuals with unresectable liver metastases from colorectal cancer amenable to locoregional therapy includes 1 RCT, a number of nonrandomized comparative studies and noncomparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, and treatment-related morbidity and mortality. The available evidence base is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
The National Comprehensive Cancer Network (NCCN) indicates that ablative techniques may be used in the treatment of certain hepatic tumors. The guideline on hepatobiliary cancer includes cryoablation in a list of ablative techniques, along with RFA, percutaneous alcohol ablation, and microwave ablation; however, the literature cited in the guideline reports on only RFA and ethanol ablation. For hepatocellular carcinoma, the guidelines recommend ablation for the following (category 2A recommendations):

- Tumors that are potentially resectable or transplantable, in patients who are operable by performance status or comorbidity, with Child-Pugh class A or B, no portal hypertension, suitable tumor location, adequate liver reserve, and suitable liver remnant.
- Tumors that are unresectable in patients who are not transplant candidates (locoregional therapy preferred).
- Tumors that are inoperable by performance status or comorbidity, with local disease or local disease with minimal extrahepatic disease only (locoregional therapy preferred).

For intrahepatic cholangiocarcinoma, the guidelines recommend locoregional therapy (including ablative therapy) the following (category 2B recommendations):

- Unresectable tumors.
- Metastatic disease.
- Post-resection with residual local disease.

NCCN guidelines on neuroendocrine tumors address the use of hepatic-directed therapies for patients with unresectable hepatic-predominant progressive metastatic neuroendocrine. These guidelines state,
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“Cytoreductive surgery or ablative therapies such as radiofrequency ablation (RFA) or cryoablation may be considered if near-complete tumor burden can be achieved” (category 2B recommendation).

NCCN guidelines on the treatment of colon cancer address the treatment of liver metastases, stating “ablative techniques may be considered alone or in conjunction with resection.” RFA, cryoablation, microwave ablation, percutaneous ethanol injection, and electrocoagulation are listed as examples of ablative therapies.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


POLICY HISTORY

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<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy statement changed from investigational to not medically necessary.</td>
</tr>
<tr>
<td>June 2012</td>
<td>Update Policy</td>
<td>Related policies added.</td>
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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy statement unchanged.</td>
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<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature search; references 4, 11, 12, 15 added.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references added, reordered or removed.</td>
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<tr>
<td>March 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through November 17, 2015;</td>
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<td>references 3-4 and 8 added. Policy statement unchanged.</td>
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